DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
Ms. Becky Ronner
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

February 13, 2015

Re: K143375
Trade/Device Name: CD HORIZON® Spinal System, Medtronic Navigated Reusable Instruments
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNH, MNI, KWP, KWQ, OLO, HBE
Dated: January 16, 2015
Received: January 20, 2015

Dear Ms. Ronner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143375

Device Name
CD HORIZON® Spinal System

Indications for Use *(Describe)*

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/ spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD HORIZON® SPIRE™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/ attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined), spondylolisthesis, trauma, and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143375

Device Name
Medtronic Navigated Reusable Instruments

Indications for Use *(Describe)*

Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC® POWEREASE™ System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) SUMMARY

MEDTRONIC Sofamor Danek USA

January 2015

Submitter:	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901)396-3133 Fax: (901) 346-9738
Contact Person	Becky Ronner Senior Regulatory Affairs Specialist Direct Telephone: (901)399-2757
Date Prepared	November 21, 2014
Common Name	Bone Screws, Rods, Set Screws, Extenders, and Drivers
Device/Trade Name	1. CD HORIZON® Spinal System 2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems
Regulatory Class, Regulation Number, Regulation Name, and Device Product Code	1. CD HORIZON® Spinal System • Class III • 21 CFR 888.3050 Spinal Interlaminal Fixation Orthosis; KWP • 21 CFR 888. 3060 Spinal Intervertebral Body Fixation Orthosis; KWQ • 21 CFR 888.3070 Pedicle Screw System; MNH, MNI, NKB, OSH 2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems • Class II • 21 CFR 882.4560 Stereoitaxic Instruments; OLO • 21 CFR 882.4310 Drills, Burs, Trephines & Accessories (Simple, Powered); HBE
Predicate Devices	1. CD HORIZON® Spinal System • K142847 CD HORIZON® Spinal System (S.E.

	10/27/2014) Primary Predicate • K091974 CD HORIZON® Spinal System (S.E 9/2/2009) • K113529 CD HORIZON® Spinal System (S.E 2/9/2011) • K132639 CD HORIZON® Spinal System (S.E 11/25/2013) • K102555 CD HORIZON® Spinal System (S.E 11/17/2010) • K141605 CD HORIZON® Spinal System (S.E 7/14/2014) 2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems • K140454 Navigated Instruments (S.E 5/22/2014) *The predicates have not been subject to a design related recall.*
Description of Device	1. The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® plates, staples and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. The subject devices include: • Bone screws • Rods • Set Screws • Extender • Extender Cap • Accessories, case, caddies trays, and lids which may be used to transport and sterilize the subject implants and instruments. The subject CD HORIZON® Spinal System device will be available in similar sizes as the predicate systems. 2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems Medtronic Navigated Reusable Screwdriver is a spine preparation instrument made of high grade stainless steel. This instrument was specifically designed for use in procedures where the use of stereotactic surgery may be

	appropriate. Placing Medtronic single-use sterile spheres on each of the NavLock™ Tracker passive stems allows a Medtronic computer-assisted surgery system such as the StealthStation® Image Guidance System to track the instruments in the surgical field. Medtronic Navigated Reusable Screwdriver is compatible with various Medtronic spinal implant systems. This screwdriver is also compatible with Medtronic's IPC® POWEREASE™ System when connected to the POWEREASE™ Driver.
Indications for Use	1. CD HORIZON® Spinal System The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion. With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below. When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis,

	kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. The CD HORIZON® SPIRE™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined), spondylolisthesis, trauma, and/or tumor. In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use. 2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR-based

	model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC® POWEREASE™ System.
Comparison of Technological Characteristics with the Predicate Devices:	1. CD HORIZON® Spinal System The CD HORIZON® Spinal System has the same fundamental technology, cobalt chrome, titanium and stainless steel material as the predicate devices. The predicate and subject devices are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic lumbar and/or sacral spine. • K142847 CD HORIZON® Spinal System (S.E. 10/27/2014) (Primary Predicate) • K091974 CD HORIZON® Spinal System (S.E 9/2/2009) • K113529 CD HORIZON® Spinal System (S.E 2/9/2011) • K132639 CD HORIZON® Spinal System (S.E 11/25/2013) • K102555 CD HORIZON® Spinal System (S.E 11/17/2010) • K141605 CD HORIZON® Spinal System (S.E 7/14/2014) 2. MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS For use with StealthStation® and IPC® POWEREASE™ Systems The subject Medtronic Navigated Reusable Instrument for use with StealthStation® and IPC® POWEREASE™ Systems has the same fundamental technology and stainless steel material as the predicate devices. The predicate and subject devices are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the

	IPC® POWEREASE™ System. • K140454 Navigated CD HORIZON® Instruments (S.E 5/22/2014)
Performance Data:	The following performance data were provided in support of substantial equivalence. **Biocompatibility** The biocompatibility evaluation for the CD HORIZON® Spinal System devices was conducted in accordance with FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" issued April, 23, 2013. The subject CD HORIZON® Spinal System bone screws, rods, and set screws are permanent implants and will be classified as permanent , >30 day body contact according to with FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The subject bone screws are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standards: • **ASTM F1537** – Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants • **ASTM F67** – Specification for Unalloyed Titanium for Surgical Implant Applications • **ASTM F136** – Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications The subject rods are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standards: • **ASTM F1537** – Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum

	Alloys for Surgical Implants The subject set screws are manufactured from identical materials as the predicate devices, in accordance with the following ASTM standards: • **ASTM F136** – Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications The CD HORIZON® Spinal System extender, Extender Cap and screwdriver are external communicating devices and are classified as limited, up to 24 hours of body contact according to with FDA's Draft Guidance for Industry and FDA Staff "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". These instruments are manufactured from the same medical grade stainless steel as the predicate devices in accordance with the following ASTM standards: • **ASTM F899** – Standard Specification for Wrought Stainless Steel for Surgical Instruments • **ASTM A564** – Standard Specification for Hot-Rolled and Cold Finished Age-Hardening Stainless Steel Bars and Shapes • **ASTM A693** – Standard Specification for Precipitation-Hardening Stainless and Heat-Resisting Steel Plate, Sheet and Stripe • **ASTM A276** – Standard Specification for Stainless Bars and Shapes The case, caddies trays, and lids used to for shipment and sterilization of instruments are manufactured from aluminum and/or radel and/or polypropylene with the brackets securing the instruments into the case/tray made of silicone and/or nylon coated stainless steel and/or polypropylene and are not patient contacting and do not require biocompatiblity testing.

	Cobalt Chrome, Commercially Pure Titanium, Titanium Alloy, and medical grade stainless steel have a long history of safe and effective use in spinal surgery and biocompatibility testing is not required and not testing was conducted. **Mechanical Testing** In accordance with, Guidance for Industry and FDA Staff – Spinal System 510(k)'s", Medtronic has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. It was determined that subject devices do not represent a new worst case. Engineering rationales were used to demonstrate substantial equivalence.
Conclusion:	Based on the risk analysis, test results, and additional supporting documentation provided in the pre-market notification, the subject CD HORIZON® Spinal System is substantially equivalent to the following predicates: • K142847, K091974, K113529, K132639, K102555, K141605 The MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS are substantially equivalent to the following predicate: • K140454